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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/22/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/909,862

Examiner

Shengjun Wang

Applicant(s)

XUE ET AL.

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-- Th MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

**Peri d f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

- 4) ☒ Claim(s) 13-16 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Receipt of applicants' amendments and remarks submitted June 16, 2003 is acknowledged.

#### *Claim Rejections 35 U.S.C. 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13-16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassels et al. (US 5,756,538, IDS).
3. Cassels et al teaches a method of treating anxiety comprising administering to the patient an effective non-toxic amount of substituted flavonoid, particularly substituted flavone, wherein the substituents may be hydroxyl group or low alkyl alkoxy groups. Cassels particularly prefer flavone wherein the 5, and 7 positions have hydroxyl substituents. See, particularly, the claims.
4. Cassels et al. does not teach expressly the employment of the flavone herein with R4 is a methoxyl groups.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to treat anxiety by employing a flavone with hydroxyl groups at 5, and 7, and a methoxyl group at 8 position (R4 as depicted by Cassels). A person of ordinary skill in the art would have been motivated to treat anxiety by employing a flavone with hydroxyl groups at 5, and 7, and a methoxyl group at 8 position (R4 as depicted by

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Cassels) because Cassels expressly prefer flavone with 5 and 7 dihydroxyl groups and methoxyl group is known to be useful as a substituent at 8 position (R4). The selection of methoxyl group herein is seen to be a selection from amongst equally suitable functional groups and as such obvious. Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388). Further, the optimization of a result effective parameter, e.g., the effective amount of a therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

***Response to the Arguemnts***

Applicants' amendments and remarks submitted June 16, 2003 have been fully considered, but are not persuasive for reasons discussed below.

Applicants' states that Cassels does not explicitly teach or provide working example of the compound herein employed. The examiner agrees. However, this alone cannot rebut the fact that a prima facie case has been established. Cassels teach a method of treating anxiety by administering a flavone having a general formula encompassing the compound herein employed (claim 1). Cassels also provide guidance and suggestion to a much narrower subgenus of the flavone, wherein R1 and R3 are hydroxyl groups (claims 4-6). In view of the teaching provide in Cassels, one of ordinary skill in the art would have reasonable expected that wogonin be useful as anti-anxiety agents.

Since a prima facie case has been established, an unexpected result reside in the claimed species would be required to rebut the obviousness. The difference of the optimal effective amounts between the preferred compound by Cassels and the compound herein employed does not constitute an unexpected result that would overcome the obviousness. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's

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burden to explain any proffered data and establish how any results therein should be taken to be unexpected and of both statistical and practical significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, it must be compared with the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (e). As stated above, it is considered within the skill of artisan to optimize the effective amounts of a therapeutical agents. Further, there is no explanation as to how such difference would be significant to the therapeutical application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

  
PATENT EXAMINER  
Shengjun Wang

August 19, 2003